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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,843	10/12/2001	Stephen H. Friend	9301-161	1315

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EXAMINER	
MARSCHEL, ARDIN H	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 05/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,843	FRIEND ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-59 and 67-84* is/are pending in the application.

~~4a) Of the above, claim(s)~~ *1-52 and 60-66 have been canceled.* ~~are withdrawn from consideration.~~

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *53-59 and 67-84* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 53-59, 67, 68, 71, 72, and 79-81; drawn to a computer system or product for determining a level of activity of a biologically active cellular constituent, via a perturbation response profile comparison to a diagnostic profile, classified in class 702, subclass 19. If this Group is elected, then the below summarized two (2) specie elections are also required.

II. Claims 69 and 70, drawn to a computer system for measuring the activity of a drug via a perturbation response profile comparison to a diagnostic profile, classified in class 702, subclass 19.

III. Claims 73, 74, and 82; drawn to a computer system or product for identifying a cell or a cell type that has one or more genetic mutations or polymorphisms that disrupt activity of one or more corresponding gene products, classified in class 702, subclass 19. If this Group is elected, then the below summarized two (2) specie elections are also required.

IV. Claims 75, 76, and 83; drawn to a computer system or product for determining the dose of one or more drugs to achieve a desired clinical effect in a patient, classified in class 702, subclass 19. If this Group is elected then the below summarized specie election is also required.

V. Claims 77, 78, and 84; drawn to a computer system or product for determining drug therapy to achieve a desired clinical effect in a patient,

classified in class 702, subclass 19. If this Group is elected then the below summarized specie election is also required.

SPECIE ELECTION REQUIREMENT FOR GROUP I (FIRST), III (FIRST), IV, or V:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: Claim embodiments wherein protein(s) activity is profiled

Specie B: Claim embodiments wherein a non-protein active cellular constituent is profiled as elected specifically or some combination of cellular constituents to be examined as the initial profiling practice.

These species are distinct and require a separate search because the analysis and/or testing for each cellular constituent requires a different assay methodology which must be evaluated and searched separately thus documenting the undue search burden if they were searched together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 71, 72, and 81 (Group I); claims 73, 74, and 82 (Group III); claims 75, 76, and 83 (Group IV); and 77, 78, and 84 (Group V) are generic to the above listed species

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

SECOND SPECIE ELECTION REQUIREMENT FOR GROUPS I or III:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie C: Claim embodiments wherein the perturbation is a drug

Specie D: Claim embodiments wherein a generic non-drug perturbation is utilized.

These species are distinct and require a separate search because the analysis and/or testing for a drug versus a generic component or perturbation requires a different assay methodology, such as drug effect(s) on a cellular constituent versus a nutrient

requirement perturbation or other perturbation which may include UV light irradiation, temperature effects, etc., which must be evaluated and searched separately thus documenting the undue search burden if they were searched together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 53-59, 67, 68, 71, 72, 79, and 81 (Group I) and claims 73, 74, and 82 (Group III) are generic to the above listed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because:

The distinctness between species has been summarized above.

The distinctness between the computer systems or products is set forth via the systems and products having different functions and goals thus being distinct subject matter requiring separate searches which documents the undue search burden if any two or more Groups are searched together. Group I is directed to determination of the activity level per se of a cellular constituent via perturbation profiling. Group II is directed to measuring a drug activity level. Group III is directed to identifying a cell type with one or more mutations or polymorphisms. Group IV is directed to drug dose determination. Group V is directed to the determination of drug therapy for obtaining a desired clinical effect. Thus, these Groups are directed to distinct inventions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful; the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 7, 2003

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER